

November 2007

Background

The Hospital Licensing Reform Steering Committee was convened in November 2006 to develop recommendations for implementing a reform agenda for hospital licensing policies and practices. The reform agenda had been jointly established by Maine hospitals and the Division of Licensing and Regulatory Services (DLRS) within the Department of Health and Human Services (DHHS), through a collaborative process.

The foundation for this process was laid through the work of the Administrative Procedures Oversight Committee (APOC), which was established to align the mission and activities of the Department's operations and support functions with DHHS transformational goals, including customer service, collaborative approaches within and outside government, and the application of evidence-based practices to guide service delivery. Over the course of six months, with the participation of more than 40 DHHS staff and community stakeholders, the APOC developed concrete recommendations for improving the Department's licensing, contracting and auditing functions.

Beginning in February 2006, the DLRS asked the Muskie School of Public Service at the University of Southern Maine to facilitate a process for identifying strategies to bring the hospital survey process into closer alignment with DHHS guiding principles. Through a series of three discussion groups, one with hospitals, one with licensing staff, and a third, joint meeting, a series of reform priorities were identified. These priorities were documented in an August 2007 report from the Muskie School to the Maine Hospital Licensing Review Board.

Following up on this earlier process, in November 2006 DLRS convened the Hospital Licensing Reform Steering Committee. See MEMBERSHIP at ATTACHMENT A. The Steering Committee was asked to:

- Build on the work and recommendations already developed in previous efforts to identify what reform is needed.
- Develop a work plan with specific timelines and outcomes to guide reform activities.
- Make recommendations in guidance of the design and implementation of licensure reform.
- Prepare a communications strategy to ensure stakeholder involvement in all phases of this initiative.

See STEERING COMMITTEE CHARGE at ATTACHMENT B. The reform priorities identified in the earlier process were translated into a series of action statements, reviewed, refined and prioritized by the Steering Committee. See the Steering Committee's REFORM AGENDA on the next page. These action statements were used by the Steering Committee to develop its work plan. The Steering Committee met monthly with plans to complete its work by fall 2008.

In June 2007, PUBLIC LAW, CHAPTER 314 was signed into law. See ATTACHMENT C. Under P.L. 314, a hospital is exempt from a licensing inspection if the hospital is certified in compliance with the federal Medicare Conditions of Participation and holds full accreditation status by an accrediting body recognized by the federal Centers for Medicare and Medicaid Services. If a hospital is Medicare certified but not accredited, the hospital is inspected every three years for compliance with the Conditions of Participation. The Department may also conduct an inspection in response to a complaint or suspected violation of federal condition of participation or a hospital licensing statute.

Hospital Licensing Steering Committee Reform Agenda

1. Develop a state-of-the-art survey process that:

- Uses available data, including complaint data, to target the scope and intensity of licensure surveys.
 - Applies the tracer model to assess compliance with standards.
 - Is coordinated with surveys conducted for Medicare Conditions of Participation and JCAHO and other accreditation organizations to eliminate unnecessary duplication and inconsistency.
 - Reflects the appropriate balance between the Department's role as consultant and enforcer
2. Develop a state-of-the-art regulatory framework that:
 - Is outcome-oriented and based on evidence of processes and structures that are known to impact quality.
 - Is regularly updated through a collaborative process to support best practices.
 - Is aligned with federal and other state regulatory requirements, and national accrediting standards, to eliminate unnecessary duplication and inconsistency.
 - Allows the Department to deem a hospital with JCAHO or other appropriate accreditation in compliance with comparable state licensing requirements.
 - Clearly defines expectations to enable consistent interpretation across surveyors and hospitals
 - Includes peer review protections
 - Provides a self-assessment tool coordinated with JCAHO
 3. Create a range of enforcement tools that:
 - Permit the State a range of options in addressing issues of noncompliance.
 4. Develop a communications strategy among the Department, hospitals, and consumers that:
 - Is premised on a common appreciation for each stakeholder's commitment to improving the quality and safety of Maine hospitals.
 - Promotes shared learning and joint problem solving to advance quality improvement.
 - Relies on multiple mechanisms to assure continued communication, including: a joint committee to oversee the on-going process of updating standards, reviewing survey processes, refining quality indicators and data collection, etc.; electronic tools to widely communicate regulatory requirements and changes and to promote the efficiency of the regulatory process.
 5. Define education and professional development standards that:
 - Are supported by the Department's commitment to sufficiently invest in professional development for survey staff
 - Identify desired credentials and training for survey staff
 - Promote joint trainings and educational opportunities for surveyors and hospital staff to cultivate common understanding of regulatory requirements and promote mutual respect and understanding
 6. Review and revise the complaint process, making recommendations that:
 - Build on agency's internal complaint findings
 - Separate incidents from complaints
 - Standardize minimum information from hospitals
 - Use outcomes to focus and target survey process (see #1)

From the perspective of hospitals participating on the Steering Committee, this legislation precludes the added value of separate state licensing regulation. As a result, from the hospitals' perspective, the scope of work connected to Action Statement #2 (Develop a state-of-the-art regulatory framework) has been significantly reduced. From the perspective of DLRS members, for hospitals with Medicare certification, P.L. 314

eliminates the need for a state licensing survey against state standards but does not eliminate the need for state standards, which DLRS sees as applicable for complaint investigations and other regulatory requirements specified under state statute.

This report summarizes the work and recommendations connected to each of the Steering Committee's action statements. The recommendations emerging from the Steering Committee will be presented to the Maine Hospital Licensing Review Board for their consideration. In addition, other stakeholders will have an opportunity to weigh in on the reform agenda addressed through this process.

Recommendations

1. Survey Process

The Steering Committee formed a Data Subcommittee to identify, review and recommend data that should be used to inform and strengthen the hospital survey process; develop a framework for how data can be used to improve the effectiveness and efficiency of the hospital survey process; determine the applicability of proposed data to hospitals of various sizes and specialties; define regulatory, disclosure, or other barriers to using proposed data in the hospital survey process; and proposed protocols for using data in the hospital survey process.

Based on the subcommittee's findings, the Steering Committee recommends that the following types of data be used to inform a state survey:

- Substantiated complaint data
- The 26 quality indicators currently available on CMS' website
- Specific volume data: the top 15 DRGs for inpatient services, the top 20 CPTs for outpatient services, and 6 indicators for low volume and high risk procedures.

The Steering Committee cautions that, when interpreting these data, the Department should take advantage of available expertise (*e.g.*, the Maine Quality Forum), to ensure that it is interpreting the data appropriately.

The Steering Committee could not reach consensus on whether or not the Joint Commission's final report should be available when the Department is reviewing accredited hospitals. Some members believe that, once deemed, it is not necessary to second guess the Joint Commission's findings. Others believe that reviewing the final report would be due diligence for the State. The Department notes that under the new legislation, if a hospital is accredited, the Department conducts no onsite survey and has no information on hospital performance, unless it obtains a copy of the Joint Commission's report.

The Steering Committee also encourages the Department to pursue access to some of the Joint Commission's tools (*e.g.*, root cause analysis or medication reconciliation work sheets), or tools developed by other accrediting bodies, so that these and other best practice tools can be made available to non-accredited hospitals. The Steering Committee also recommends that the licensing application be revised so that the information can be clearer for hospitals and more useful for surveyors.

2. Regulatory Framework

The Steering Committee considered alternative approaches to organizing licensing standards, (*i.e.*, the "table of contents" for licensing regulations) including that of the Joint Commission, the Medicare Conditions of Participation, the existing organization of Maine licensing standards, and the approaches used by other states. Because, all Maine hospitals are required to comply with the Conditions of Participation, and compliance with the Joint Commission is voluntary, Steering Committee members agreed that the Conditions of Participation were the logical organizational framework for hospital regulation.

Originally, the Steering Committee planned to align federal, state and accrediting standards to eliminate inconsistency and minimize unnecessarily duplicative standards. With the enactment of P.L. 314, the hospitals participating on the Steering Committee viewed this effort as unnecessary. From the hospitals' perspective, P.L. 314 precludes the added value of state regulation.

3. Enforcement Tools

The Steering Committee considered the appropriateness of a "directed plan of correction" as an intermediate enforcement tool, short of a conditional license. The terms of a directed plan of correction would be defined by the Department. Currently, the directed plan of correction is used for other regulated entities. Many members agreed that a conditional license has a very negative impact on a hospital and the confidence community members have in the hospital. However, some questioned why a second plan of correction would be necessary, beyond the plan submitted to CMS and driven by the COP's. As an alternate option the state could accept the CMS approved plan with the understanding that the state can return in 2 or 6 months to monitor follow-through. In the end, the Steering Committee was unable to satisfy itself that a directed plan of correction would be an appropriate intermediate tool and refrains from making a recommendation.

4. Communications Strategy

A Communications Subcommittee was formed to address two objectives:

- To create a two-way communication system for promoting stakeholder participation in, and increasing stakeholder awareness of, the licensing reform process.
- To create an on-going system for routine communication between DHHS and Providers regarding regulatory changes and interpretations.

For its own work, the Steering Committee identified three tiers of stakeholders, as follows:

Tier 1: Tier 1 includes the vast majority of stakeholders. These stakeholders will not be formally invited to participate in the process but have the opportunity to stay informed about Steering Committee activities by "pulling" information from the Department's website.

Tier 2: Tier 2 includes stakeholders from whom "buy in" is critical (*e.g.*, hospital CEOs). For this group, the Steering Committee agreed that direct mailings or other types of "push" communication would be appropriate at various points in the process (*e.g.*, to alert stakeholders to important new materials posted on the website; to invite comment at key decision points; or to provide regular, routine updates).

Tier 3: Tier 3 includes those stakeholders asked to formally participate in the process at specified points in time, either in the role of consultant or as representatives of particular perspectives that are of interest to the Committee. Examples of Tier 3 stakeholders include subject-matter experts engaged to review specialized licensing standards or the Maine Quality Forum to consult on performance data. The Subcommittee acknowledged that a more challenging question is how to incorporate the interests of the public or of specific consumer groups.

The Communications subcommittee recommended that its meeting agendas, minutes, draft products, final products, research, etc., would all be posted on the Department's website.

For ongoing communications, the Steering Committee makes the following recommendations:

Public Access: The following information should be publicly available through the Department's website:

- Licensing standards
- Interpretive guidelines
- Notice of proposed changes to standards
- Link to hospital quality data

Restricted Access: The following information and functionality should also be available through the Department's website.

- Licensing application (with the capacity to complete, and preferably submit, online)
- Licensing reapplication (with the capacity to complete, and preferably submit, online)
- Licensing findings
- Response to licensing findings (electronic action report submitted online)
- Frequently asked Questions
- Recent interpretations or findings to be shared
- Training calendar (electronic registration)

Listserve: The Department should maintain a list serve for posting policy updates and proposed changes to standards.

Formal Notifications: In addition to the list serve, the Department should also maintain a subscription list of hospitals to receive direct notification of policy updates.

5. Education and Professional Development Standards for Surveyors

The Steering Committee makes the following recommendations regarding the qualifications and professional development for surveyors:

- Surveyors' skills and experience should include an acute care background; critical thinking; good writing; the ability to work independently; analytical skills, including the ability to analyze data; prior experience monitoring compliance; and prior supervisory experience.
- Surveyor credentials are also important. Preferred credentials would include nurses, preferably at a master's level, but a bachelors at a minimum; a bachelor level medical technologist; or a professional certified in healthcare quality.
- Surveyors should have ongoing internal training to promote the consistent application of standards across hospitals. New surveyors should have a "How to be a Surveyor 101" training course, to help them transition from a clinical practice to the surveyor role.
- Joint trainings with hospital and licensing staff, or a hospital's in-house training opened to include licensing staff. would be another mechanism for providing professional development opportunities for surveyors.

6. Complaint Process

The Steering Committee formed a Complaints Subcommittee to develop recommendations for reforming the current approach to responding to hospital complaints. Initially, the subcommittee was comprised of five Steering Committee members, representing large hospital systems, a critical access hospital, a psychiatric hospital and a representative of the departmental licensing staff in charge of complaint investigations. In subsequent meetings, the subcommittee expanded to include a complaint director from one of the member hospitals and two consumer representatives, a former long term care ombudsman and a mental health consumer advocate. Based on the report of this subcommittee, the Steering Committee makes the following recommendations:

Changes in law and regulation. Make two changes to existing law to improve response time and reduce backlog:

- Revise existing regulation to make unannounced complaint investigations discretionary. Currently, it is mandatory that the Department give no notice, preventing the hospital from addressing the complaint without an investigation.

- Impose a time limit for submitting complaints, within one year of the event. Allow the Department to accept older complaints at its discretion.

Create a multi-tiered complaint intake process. The Department's process for accepting complaints should be modified to encourage resolution by the hospital, with Department involvement only when necessary. The following modified process is recommended:

- The Department's intake officer will document previous efforts by the complainant to resolve the complaint at the hospital level; depending on the objectives of the complaint, the intake officer may offer to facilitate resolution of complaint with the hospital, rather than initiating a complaint investigation;
- For complaints categorized as medium, low or administrative by the intake officer, the Department will seek the complainant's consent to disclose the complaint to the hospital, so that the hospital may conduct its own investigation. Immediate jeopardy or high jeopardy complaints may continue to be subject to unannounced complaint investigations at the discretion of the Department;
- For those complaints for which the hospitals will be asked to provide evidence of their own investigation, the Department will determine, based on the hospital response and other evidence, whether further on-site investigation by Department staff will be required to determine whether the complaint is substantiated or not. If substantiated, the Department will determine whether appropriate corrective measures have been instituted by the hospital.
- The Department may advise complainants who insist on anonymity that a response to their complaints may face significant delay; anonymous complaints may require investigation by Department personnel directly rather than referral to the hospital's self-regulated complaint process.

Set standards for how hospitals investigate and address complaints. Because DLRS is delegating to hospitals responsibility for addressing medium, low and administrative complaints, DLRS should set standards for how hospitals self-monitor and self-regulate complaints. Hospitals will be expected to respond to the Department's request for information about a complaint investigation by providing responses according to a specified format. Hospitals will also confirm that their hospital complaint personnel have received adequate training on the process for receiving, documenting and investigating complaints. The Department should develop its standards for hospital complaint investigation and "adequate training" in collaboration with hospitals, many of which already have a defined approach.

Conduct a public education campaign. The public needs a better understanding of the objectives of a complaint investigation conducted by DLRS. The public also needs information about other agencies and resources when a complaint does not fit within DLRS' jurisdiction. This public education campaign should include:

- Consumer communications, hospital literature, and website links, providing information and resources about appropriate avenues for lodging a complaint. The information should explain appropriate categories of complaints to submit to the Department and clarify reasonable expectations for complaint resolution. Materials should be readily available to patients.
- Confidential web-based electronic complaint submissions.
- An intake process that guides complainants to other agencies, when the complaint is not appropriately addressed by DLRS.
- Annual dissemination of substantiated complaint data to the public.

Expand resources for complaint investigations. Currently DLRS does not have adequate resources for conducting complaint investigations and is experiencing a significant backlog. To expand the Department's capacity the following recommendations are made:

- Enhance technology to provide offsite and internet access for investigators to work efficiently across the state;

- Budget for and IT interface (between ASPEN and Departmental database systems) to allow personnel to track and trend complaint data for hospitals and as a measure of quality control.
- Budget for continuing educational offerings for staff and hospital complaint personnel.

ATTACHMENT A

Hospital Licensing Reform Steering Committee
MEMBERSHIP

Linda Abernethy
Dorothea Dix Psychiatric Hospital

Mary Finnegan
Goodall Hospital

Julie Marston
Maine Medical Center

Annette Adams
Acadia Hospital

Lynne Gagnon
Mayo Regional Hospital

Sandra Parker
Maine Hospital Association

Laura Benson
Spring Harbor Hospital

Melissa Gallant
St Andrews Hospital

Maureen Parkin
Southern Maine Medical Center

Sue Boisvert
Parkview Adventist Medical Center

Denise Gay
Maine General Medical Center

Sherry Rogers
Redington-Fairview General Hospital

Kathy Bonney
Stephens Memorial Hospital

Cindy Juchnik
Miles Health Care

Judy Street
St Joseph's Hospital

Dianne M. Bubar
Eastern Maine Medical Center

Sharon King
Sebasticook Valley Hospital

Bill Zuber
Penobscot Bay Medical Center

Gerry Cayer
Franklin Memorial Hospital

Sally Lewin
York Hospital

Catherine Cobb
DHHS

Laird Covey
Central Maine Medical Center

Ruth Lyons
Mount Desert Island Hospital

Denise Osgood
DHHS

Beth Dodge
Down East Community Hospital

Missy Marter
Millinocket Regional Hospital

Catherine Valcourt
DHHS

Stacey Doten
Calais Regional Hospital

Hospital Licensing Reform Steering Committee

CHARGE

The enabling legislation authorizing the creation of the Department of Health and Human Services (DHHS) stressed a renewed commitment to customer service, collaborative approaches within and outside government, and the application of evidence-based practices to guide service delivery. The Administrative Procedures Oversight Committee (APOC) was established to align the mission and activities of Operations and Support with DHHS transformational goals. As part of that process the Licensing Subcommittee developed a statement of vision, mission and guiding principles to govern the Division of Licensing and Regulatory Services operations, and several recommendations for policy and process improvement. Since February 2006, the Department has been working with hospitals to identify strategies to bring the hospital survey process to into closer alignment with DHHS guiding principles. As a result of this work, the hospitals and the Department identified several strategies for reforming the State's role in hospital licensing in Maine. They agreed to form a Steering Committee to oversee the design and implementation of licensure reform.

The Steering Committee will:

- Build on the work and recommendations already developed in previous efforts to identify what reform is needed.
- Develop a work plan with specific timelines and outcomes to guide reform activities.
- Make recommendations in guidance of the design and implementation of licensure reform.
- Prepare a communications strategy to ensure stakeholder involvement in all phases of this initiative.

ATTACHMENT C

PUBLIC Law, Chapter 314, 123rd Maine State Legislature
An Act To Prevent Duplication in Certification of Hospitals

An Act To Prevent Duplication in Certification of Hospitals

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1816, as amended by PL 1997, c. 488, §2, is further amended by adding at the end a new paragraph to read:

A hospital licensed under this chapter is exempt from department inspection requirements under this chapter if the hospital is certified by the Centers for Medicare and Medicaid Services for participation in the federal Medicare program and holds full accreditation status by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services. If a hospital is certified to participate in the federal Medicare program and not accredited by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services, the department shall inspect the hospital every 3 years for compliance with the Centers for Medicare and Medicaid Services' conditions of participation. The provisions of this paragraph do not exempt a hospital from an inspection by the department in response to a complaint or suspected violation of this chapter or of the Centers for Medicare and Medicaid Services' conditions of participation or an inspection by another state agency or municipality for building code, fire code, life safety code or other purposes unrelated to health care facility licensing or accreditation. For purposes of this paragraph, "Centers for Medicare and Medicaid Services" means the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Sec. 2. Effective date. This Act takes effect July 1, 2008.